

SEP 29 1998

510(k) SUMMARY

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K981834.

1. Submitter's Identification :

Perception Inc.
9344 N.W. 13th Street, Suite 200
Miami, Florida 33172
Contact Person : Mr. Jorge Millan

Date Summary Prepared: April 17, 1998

2. Name of the Device :

Perception Inc. GPS-6TBMD Diagnostic Ultrasound System

3. Predicate Device Information :

1. **Aloka Co.**
Model SSD-1700 K963616
2. **Diasonics Ultrasound**
Models { Synergy K935024
 CFM800 K924079
 EchoPac K962662
3. **Perception Inc.**
Model GPS-TUV K#972973.
Model GPS-XYZ K#972192
4. **Pie Medical**
Model Ultrasound
 Scanner #1150 K#900469
5. **International Ultrasound Co.**
Model HRI 2000 K#961229

4. Device Description :

General Description

The Perception's GPS-6TBMD Ultrasound System is a PC (computer) based and controlled real time, two dimensional, mechanical sector and electronic array diagnostic ultrasound and pulsed Doppler imaging system which produces diagnostic ultrasonic images and blood flow spectral analysis through user friendly operation.

The following intended uses are identified for the transducer applications: General Radiology, Urology, Abdominal, Cardiac, Trans-vaginal, Trans-rectal, Vascular, Small Organs, Breast, Thyroid, Fetal Imaging and Musculo-Skeletal (conventional) with the use of ultrasonic probes from 3.0-12.5 MHz. There are no transcranial applications for this device.

User interface is via an alphanumeric keypad, trackball and Icon-driven graphical interface. The Perception Inc. GPS-6TBMD Diagnostic Ultrasound System may be operated in M /B /D modes of inspection. The Perception GPS-6TBMD Diagnostic Ultrasound System supports M, B, M&B, Dual B, Quad B, D and D/B, display modes.

All probes currently intended for use with the Perception GPS-6TBMD Diagnostic Ultrasound System are either mechanical sector devices or electronic linear and curve array, and make use of a fluid filled design. Transducer parameters are summarized in the following table:

App/Prob/ Freq(MHz)	GP-3.0 2.8	CA-3.5 3.5	EV-6.5 6.5	ER-6.5 6.5	LA-7.5 6.5	PV-12.5 12.5
Abdominal	M/B/PWD	B/PWD				
Cardiac	M/B/PWD	B/PWD				
Vascular					M/B/PWD	M/B
Trans-rect				B		
Trans-vag			M/B			
Small Organ Breast, Thyroid, Testes, Musculo- skeletal	M/B/PWD	B/PWD			B	B
Fetal	M/B	B	M/B			

5. Intended Use:

See Attachment.

6. Comparison to Predicate Devices:

We believe the Perception Inc. GPS-6TBMD Diagnostic Ultrasound System to be substantially equivalent to ultrasound devices currently in commercial distribution in the U.S. A table of comparison outlining similarities and differences between the Perception Inc. GPS-6TBMD Diagnostic Ultrasound System and predicate devices is attached to this summary.

7. Discussion on Non-Clinical Test Performed for Determination of Substantial Equivalence are as Follows:

This 510(k) submission is intended as a Track 1 type submission. Acoustic Output Reporting was prepared utilizing the following documents.

- NEMA 1992, Acoustic output measurement standard for diagnostic ultrasound equipment, NEMA Standard UD-21992.
- FDA Center for Devices and Radiological Health 1985 510(k) Guide for Measuring and Reporting and Acoustic Output of Diagnostic Ultrasound Medical Devices, December 1985, Revised, 1989, 1990, 1991, 1993, 1994, and 1995.

Acoustic output of each system/transducer/mode/application combination was measured and calculated per the above documents. The following testing was conducted which revealed satisfactory testing results and compliance to applicable standards.

- Maximum Acoustic Output Information
- Estimated In-Situ Intensity
- FDA In-Situ Intensity Limits
- Acoustic Output Information for each system/transducer/mode combination

A contract-testing laboratory conducted the following testing:

- UL-544, Third Edition
- Radiated and Conducted Emissions per CISPR 11
- Magnetic Field Emissions per MIL-STD-482D, method RE101
- Electrostatic Discharge Immunity per IEC 801-2

- Radiated Field Immunity (3 V/m, 26 MHz to 1 GHz, 100% Square wave Modulation)
- Steady State Voltage Fluctuations
- Line Voltage Dropouts
- Slow Line Voltage Sags and Surges
- Fast Transients Bursts per IEC 801-4
- Fast Line Voltage Surges
- Conducted Energy Immunity per MIL-STD-462D, Method CS114
- Magnetic Field Immunity per MIL-STD-482D, Method RS 101
- Quasi-Static Electric Field Immunity

None of the testing demonstrated any design characteristics that violated the requirements of the September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, Center for Devices and Radiological Health" or resulted in any safety hazards. It was the contract testing Laboratory's conclusions that the device tested met all relevant requirements of the aforementioned guidance testing requirements.

8. Discussion of Clinical Test Performed:

Not Applicable

9. Conclusions:

The Perception Inc. GPS-6TBMD Diagnostic Ultrasound System has the same intended use as a combination of all cited predicates. All non-clinical testing and biocompatibility testing revealed no new questions of safety or effectiveness. This, when compared to the predicate devices, the Perception Inc. GPS-6TBMD Diagnostic Ultrasound System does not incorporate any significant changes in intended use, method of operations, material or design that could affect safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 29 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jorge Millan
Official Correspondent
Perception, Inc.
9344 N.W. 13th Street
Suite 200
Miami, FL 33172

Re: K981834
GPS-6TMD Diagnostic Ultrasound System
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Dated: September 10, 1998
Received: September 11, 1998

Dear Mr. Millan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GPS-6TMD Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

GP-3.0 MHz Mechanical Sector
CA-3.5 MHz Curved Array
EV-6.5 MHz Curved Array
ER-6.5 MHz Mechanical Sector
LA-7.5 MHz Linear Array
PV-12.5 MHz Mechanical Sector

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Lillian Yin
Lillian Yin, PH.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form

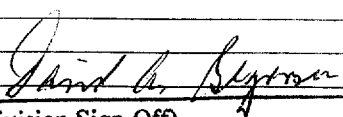
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

GPS-6TBMD – ULTRASOUND SYSTEM

Mode of Operations											
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		X	X						M+ref B		
Abdominal		X	X	X					M+ref B PWD + ref B		
Intraoperative(specify)											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)		X	X	X					M+ref B PWD + ref B		
Neonatal Cephalic											
Adult Cephalic											
Cardiac		X	X	X					M+ref B PWD + ref B		
Transesophageal											
Transrectal		X									
Transvaginal		X	X						M+ref B		
Transurethral											
Intravascular											
Peripheral Vascular		X	X	X					M+ref B PWD + ref B		
Laparoscopic											
Musculo-skeletal Conventional		X	X	X					M+ref B PWD + ref B		
Musculo-skeletal Superficial											
Other (specify)											

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: Small Organs: Breast, Thyroid, Testes.


 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use _____
(Per 21 CFR 801.109)

STO(k) Number

R981834

Diagnostic Ultrasound Indications for Use Form

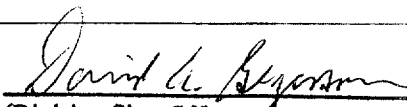
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

GP-3.0 MHz Mechanical Sector-Transducer

Mode of Operations										
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		X	X						M+ ref B	
Abdominal		X	X	X					M+ ref B PWD + ref B	
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		X	X	X					M+ ref B PWD + ref B	
Neonathal Cephalic										
Adult Cephalic										
Cardiac		X	X	X					M+ ref B PWD + ref B	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional		X	X	X					M+ ref B PWD + ref B	
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: Small Organs: Breast, Thyroid, Testes.


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

Prescription Use ☒
 (Per 21 CFR 801.109)

510(k) Number K981834

Diagnostic Ultrasound Indications for Use Form

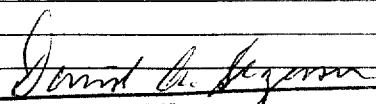
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

CA-3.5 MHz Curve Array-Transducer

Mode of Operations										
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		X								
Abdominal		X		X					PWD+ ref B	
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		X		X					PWD+ ref B	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		X	X	X					M+ ref B PWD+ ref B	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional		X		X					PWD+ ref B	
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: Small Organs: Breast, Thyroid, Testes.


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Prescription Use ☒
 (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form

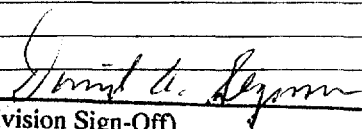
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

ER-6.5 MHz Mechanical-Transducer

Mode of Operations										
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonathal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		X								
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: NONE


 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
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Prescription Use ☒
(Per 21 CFR 801.109)

S10(k) Number

K981834

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

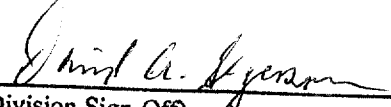
EV-6.5 MHz Curve Array-Transducer

Mode of Operations										
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		X	X						M+ ref B	
Abdominal										
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		X	X						M+ ref B	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: NONE

Prescription Use _____
(Per 21 CFR 801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
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510(k) Number K981834

Diagnostic Ultrasound Indications for Use Form

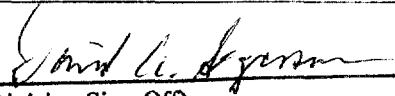
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

LA-7.5 MHz Linear Array-Transducer

Clinical Application	Mode of Operations									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		X								
Neonathal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		X	X	X					M+ ref B PWD+ ref B	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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Additional Comments: Small Organs: Breast, Thyroid, Testes.


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Diagnostic Ultrasound Indications for Use Form

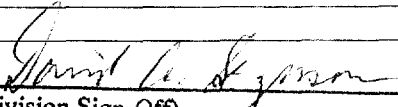
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

PV-12.5 MHz Mechanical Sector-Transducer

Mode of Operations										
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		X								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		X	X						M + ref B	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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Additional Comments: Small Organs: Breast, Thyroid, Testes.


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